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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,529

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Masahiro Toda

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BARNES & THORNBURG LLP
11 SOUTH MERIDIAN
INDIANAPOLIS, IN 46204

EXAMINER

GAMETT, DANIEL C

ART UNIT

PAPER NUMBER

1647

NOTIFICATION DATE

DELIVERY MODE

01/15/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

Office Action Summary	Application No. 10/509,529	Applicant(s) TODA ET AL.	
	Examiner DANIEL C. GAMETT	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/30/2008 has been entered.
2. Claims 4-16 are cancelled. Claims 1-3 are under examination.
3. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.
6. Amended claim 1 recites a method for inducing proliferation of an endogenous neural stem cell/neural precursor in vivo, said method consisting of contacting a nervous tissue

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comprising a neural stem cell/neural precursor and a dendritic cell with a composition consisting essentially of granulocyte-macrophage colony stimulating factor (GM-CSF). The specification as filed does not teach the concept of selecting a nervous tissue comprising a neural stem cell/neural precursor and a dendritic cell for administration of GM-CSF. In Examples 7-9, GM-CSF was administered to injured spinal cord immediately after injury. Dendritic cells were not detected in normal spinal cords, and dendritic cells were detected in injured spinal cords only seven days after injury. The results are interpreted as indicating that, whereas it has been considered that dendritic cells are not present in the normal central nervous system, dendritic cells are induced to the central nervous system by injury and that much more dendritic cells are induced by administration of GM-CSF (FIG. 15 and [0083] in the published application).

7. The Examiner notes that the amendment under consideration was made in response to the rejection under 35 U.S.C. 112, first paragraph set forth in paragraphs 6-10 in the office action mailed 08/01/2008. The rejection of record found that it is not clear that a method of stimulating proliferation of neural stem cells/precursors, wherein GM-CSF can act as the sole essential agent in the absence of cells other than neural stem cells/neural precursors would ever be achieved. In light of the disclosed results, administration of GM-CSF to tissue that comprises both neural stem cells and dendritic cells would mostly likely stimulate proliferation of the neural stem cells. Thus, the method of amended claim 1 would meet the enablement requirement of 35 U.S.C. 112, first paragraph. The Examiner suggests that a method that recites administration of GM-CSF locally to a site of injury to tissue comprising a neural stem cell/neural precursor would be both described and enabled by the instant disclosure.

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8. Amended claim 3 recites a method for inducing proliferation of a neural stem cell/neural precursor, comprising isolating a mammalian nervous tissue comprising the neural stem cell/neural precursor and a dendritic cell, culturing the neural stem cell/neural precursor and dendritic cell in a culture medium comprising a growth factor, and then co-culturing the neural stem cell/neural precursor and dendritic cell in the presence of granulocyte- macrophage colony stimulating factor (GM-CSF). The specification as filed does not teach the concept of selecting a single nervous tissue comprising a neural stem cell/neural precursor and a dendritic cell as the source for both cell types to be co-cultured. In Examples 5 and 6, neural stem cells were obtained from the putamen-corpus striatum sites of C57BL/6 fetuses, and the dendritic cells were obtained from the CD11c-positive subset was isolated from the spleens of mature C57BL/6 female mice ([0074-0079] in the published application). Thus, while it was necessary to recite the presence of dendritic cells in the co-culture in order to obviate rejections of record, the recitation of dendritic cells in the source tissues is new matter not supported by the specification. Applicants are advised that amendment of claim 3 to overcome the instant rejection may result in a substantial duplication of claim 2.

Conclusion

9. Claim 2 is allowable.

10. Claims 1 and 3 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD., whose telephone number is (571)272-1853. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel C Gamett/
Examiner, Art Unit 1647